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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,523	10/15/2003	Florian Lang	WWELL73.007AUS	5237

20995 7590 08/15/2005

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EXAMINER
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CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/687,523

Applicant(s)

LANG ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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This Office Action is in response to the paper filed June 23, 2005.

Claim 1-11 and 18-26 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 12-17 are under examination.

Priority is to October 15, 2003.

**Withdrawal of Objections:**

The objection to the disclosure because it contained an embedded hyperlink and/or other form of browser-executable code is withdrawn.

**Maintenance of Rejections:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 12, there is no reference SEQ ID NO: for amino acid position 481 and therefore it is not clear what the peptide derived from ClCKb protein having a mutation at position 481 will look like. It is not clear what activity is being modulated, rendering the method of claim 12 indefinite as to how to perform it.

Also in Claim 12, it is not clear how a peptide will have chloride ion channel activity, for example. The amendment to Claim 12 to recite polypeptide does not remediate this issue because Applicants have now redefined polypeptide to include fragments of the full-length chloride channel. Chloride channels, such as the CLC chloride channels, are large proteins comprising thousands of amino acids, and transversing membranes 10-12 times (See Waldegger

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et al. 2000; J. Am. Soc. Nephrol. 11: 1331-1339, esp. Figure 1). Thus, it is not clear what is intended by the term "polypeptide" in this context because a 100 amino acid peptide would not be expected to have chloride ion channel activity.

It follows, then, that Claims 15-17 do not find antecedent basis in Claim 12 because a 100 amino acid peptide would not be able to form a pore for a chloride channel to enable ion current to pass through it.

Applicants urge that the CICKb sequence is published in GenBank and therefore position 481 is definite. This sequence is essential matter. Therefore, this sequence must be brought into the specification via the sequence rules, 35 CFR 1.821+, and the claims amended to recite the sequence identifier.

Applicants have changed "peptide" to -- polypeptide -- yet define the polypeptide as a peptide or fragment of the CICKb sequence. Thus, this rejection is maintained for the reasons of record.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification teaches how to measure ion conductance across membranes comprising the full-length CICKb T481S. However, there is no written description regarding how to

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measure ion conductance across membranes comprising a peptide of less than 100 amino acids derived from ClCKb and comprising the T481S mutation. The amendment to Claim 12 to recite polypeptide does not remediate this issue because Applicants have now redefined polypeptide to include fragments of the full-length chloride channel. Chloride channels, such as the CLC chloride channels, are large proteins comprising thousands of amino acids, and transversing membranes 10-12 times (See Waldegger et al. 2000; J. Am. Soc. Nephrol. 11: 1331-1339, esp. Figure 1). Thus, a 100 amino acid peptide would not be expected to have chloride ion channel activity and the specification lacks written description of such.

Applicants discuss their definition of peptide versus polypeptide but do not address the issue of written description for the claimed method using fragments of the full-length ClCKb.

Applicants may wish to amend Claim 12 as follows:

A method for identifying substances modulating the [activity] reabsorption of sodium chloride by a [polypeptide derived from] chloride channel Kb (ClCKb) protein, wherein said protein is genetically altered at amino acid position 481 compared to wild-type (SEQ ID NO: X), comprising the steps of:

(a) contacting said [polypeptide] protein with a test substance, under conditions allowing the binding of said test substance to said [polypeptide] protein, and

(b) determining whether said test substances modulates [the activity of said polypeptide] reabsorption of sodium chloride by said protein.[,

wherein said polypeptide protein comprises said amino acid as position 481 of the ClCKb protein.]

No Claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

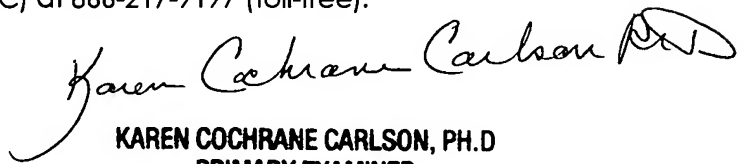
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER